March 4, 2003

Stewart H. Miller
Product Regulatory Affairs Manager
Cabot Corporation
75 State Street
Boston, MA 02109

Dear Mr. Miller:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Silane, Dichlorodimethyl- posted on the ChemRTK HPV Challenge Program Web site on November 4, 2002. I commend the Cabot Corporation, Degussa AG, and Wacker-Chemie, GmbH for their commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that you advise the Agency, within 60 days of this posting on the Web site, of any modifications to the submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-*S*-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:**
**Dichlorodimethylsilane Reaction Products with Silica**

## Summary of EPA Comments

The sponsors, Cabot Corporation, Degussa AG and Wacker-Chemie, GmbH, submitted a test plan and robust summaries to EPA for dichlorodimethylsilane reaction products with silica (CAS No. 68611-44-9) dated September 15, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on November 4, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

2. Health Effects. Except for the reproductive/developmental toxicity endpoint, all appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program. EPA suggests that a combined reproductive/developmental toxicity study be conducted.

3. Ecological Effects. All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

## EPA Comments on the Dichlorodimethylsilane Reaction Products With Silica Challenge Submission

### Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program except for the reproductive/developmental toxicity endpoint.

Because inhalation and oral feed studies were performed, it would be useful to know the generic use, or at least the expected route of exposure in humans, to better inform the analysis of existing data and possible data gaps.

*Repeated-Dose Toxicity*. EPA believes that, taken together, the number of repeated-dose studies, although individually deficient largely because they are all single dose studies, are adequate for the

purposes of the HPV Challenge Program. However, the dose levels (in mg per kg per body weight of animal) need to be clarified in the oral studies (see Specific Comments on Robust Summaries below).

*Reproductive/Developmental Toxicity*. EPA believes that the "fertility/pre-natal" study (page 51 in the submission) does not meet the reproductive/developmental toxicity requirement because: (1) only one dose level was used and (2) the study protocol used a very different male-to-female mating ratio than is acceptable (1:5 versus 1:1 or 1:2). This latter point becomes more important because the study tested only two males and 10 females. Clarification of the reproductive endpoint is especially important because testicular atrophy was observed in one male in the two-year feeding study.

Thus, the combination of only one dose, a low number of animals used, and a male:female ratio for mating which is inappropriate renders this study inadequate for the purposes of the HPV Challenge Program. EPA suggests that a combined reproductive/developmental study, such as OECD Test Guideline 421, be performed.

Ecological Effects (fish, invertebrates, and algae)

The submitted studies had a number of methodological problems. However, because this chemical polymerizes to water-insoluble substances, it is not expected to be toxic to aquatic organisms at the limit of its water solubility. Therefore, for this reason, all appropriate SIDS-level endpoints have been addressed.

**Specific Comments on the Robust Summaries**

Health Effects

*Acute Toxicity.* A robust summary for an acute oral test in dietarily-exposed rats (page 17) omitted the following details: the size of the body weight gain reduction in the single affected female and the sex of the animal that showed a lung adhesion at necropsy.

*Genetic Toxicity.* The robust summary for an in vitro assay (page 50) did not identify the bacteria used; only the strains were described–WP2 uvr strain and TA 98, TA 100, and TA 1537. The summary needs to include the genus and species (*Escherichia coli* and *Salmonella typhimurium,* respectively).

*Repeated-Dose Toxicity*. The submitter needs to clarify whether the doses listed in the oral studies represent the concentration in feed (as implied) or whether they truly are the dose received by the animal on a mg test substance per kg of body weight basis. If the actual doses were not measured or provided in the original technical report, estimated values expressed on a mg test substance per kg of body weight basis need to be provided in the robust summaries.

Ecological Effects

*Algae.* The robust summary refers to an attachment ("ref11.xls") for cell density data, but no attachment was submitted.

**Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.